



Atty. Docket No.: 204231/2055 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Liew C.C.
Serial No.: 10/601,518
Filed: June 20, 2003
Entitled: Method for the Detection of Gene
Transcripts in Blood and Uses Thereof

Examiner: Switzer, J

Group Art Unit: 1634

Conf. No.: 5174

CERTIFICATE OF MAILING UNDER 37 CFR 1.10

I hereby certify that the paper (and any paper or fee referred to as being enclosed) is being deposited with the United States Postal Service using Express Mail to Addressee Service, under 37 C.F.R. Section 1.10, **Express Mail Label No. EV888715307US** on this date, **November 14, 2006**, postage prepaid, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Andrea MacVarish

Name of Person Mailing

Andrea MacVarish

Signature of Person Mailing Paper

**Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

STATEMENT OF SUBSTANCE OF EXAMINER INTERVIEW

Sir:

This is filed in response to the Interview Summary mailed September 25, 2006.

Applicant thanks Examiner Juliet Switzer for the courtesy of a productive telephone interview on September 14, 2006 with Kathleen Williams, Lesley Rapaport, Gailina Liew, Alain Bendavid and Amy DeCloux. The following points were discussed:

The first office action on the merits was discussed. The Examiner agreed that amendments which recite "in RNA from a blood sample which has not been fractionated into cell types" and "in RNA from unfractionated cells of a lysed blood sample" would overcome the 35 U.S.C. § 112, 2nd paragraph rejections of record.

Applicant pointed to Example 6, paragraph 58, paragraph 77 and paragraph 79 of the parent specification (U.S. Pub. 20040014059) as providing written support for the claim amendment that recites "said subjects having said disease are asymptomatic with respect to said

disease”. The Examiner agreed that paragraph 79 provided support for the amendment. The Examiner commented that we may wish to amend the language to more closely reflect paragraph 79 language by using “overt symptoms” terminology in place of “asymptomatic”.

Applicant indicated that Sharma teaches the necessity of using non sequence specific methods, and amendments in view of this teaching by Sharma were discussed. The Examiner suggested including language in the claims that recites that primers are used that are specific to a particular gene or language that recites features of the primers that distinguish the primers used in the claim methods from those used in Sharma. The Examiner explained that primers used to amplify mRNA (e.g. oligo dT) are considered by her to be within the scope of the simple recitation “gene specific primers” under the broadest reasonable interpretation of the claims.

Finally, the 35 U.S.C. § 103 rejections based on the Nagai et al. reference were discussed. Applicant pointed out that the lymphocytes utilized by Nagai represent as little as 15% of the nucleated, RNA-expressing cells in blood. Applicant clarified that the majority of the nucleated, RNA-expressing cells of blood are in fact polymorphonuclear cells, which are excluded by Nagai. The Examiner raised the Wong reference, which she had just cited against a pending case by Applicant (10/803,648). The Examiner explained that the reference deals with liver cancer and looking at RNA levels in monocytes. Applicant explained that monocytes also represent a minority of the nucleated, RNA-expressing cells of blood. It was agreed that Applicant would provide further arguments regarding the composition of blood and how this is relevant to the fact that Nagai’s data is based only on the gene expression of lymphocytes as opposed to the gene expression of other cells included in the samples utilized by Applicant. The Examiner indicated that she would give these arguments further consideration.

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It is believed that no fees are due. However, if overlooked, the Commissioner for Patents is hereby authorized to charge all fees in the total amount to Deposit Account 04-1105, Reference No. 204231/2055.

Respectfully submitted,

Date: November 14, 2006

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Alexandria, VA 22313-1450

COVER LETTER

Sir:

The documents filed herewith are being filed to replace the Amendment and Reply filed yesterday in response to the Non-Final Office Action mailed from the U.S. Patent and Trademark Office on August 11, 2006 and further to the interview with the Examiner conducted September 14, 2006. We believe a complete response was filed with the USPTO yesterday, but our file copies indicate the possibility that a page of the response may be missing.

If in fact, a complete response was not filed yesterday, Applicant respectfully petitions under 37 C.F.R. § 1.136(a) for an Extension of Time of one month to file a Response in the above-identified patent application. This will serve to extend the time for filing the Response to the Non-Final Office Action mailed August 11, 2006 from November 11, 2006, up to and including December 11, 2006.

The Commissioner for Patents is hereby authorized to charge any and all fees in the total amount or credit any overpayment to Deposit Account 04-1105, Reference No. 204231/2055. A duplicate of this letter is enclosed for that purpose.

Date:

Nov 14, 2006

Respectfully submitted,

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TRANSMITTAL LETTER

Enclosed for filing in the above-identified patent application, please find the following documents :

1. Cover Letter;
2. Replacement Amendment and Reply to Office Action mailed August 11, 2006;
3. Appendices 1 through 4
4. Statement of Substance of Examiner;
5. Petition for Extension of Time (One Month); and
6. Return Post Card.

The Commissioner for Patents is hereby authorized to charge any fees to Deposit Account No. 04-1105, Reference 204231/2055. A duplicate of this transmittal letter is enclosed for this purpose.

Respectfully submitted,

Date: November 14, 2006

Amy DeCloux 54844 *Amy DeCloux*
for

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